Managing patients with cardiac implantable electrophysiological devices (CIED) infections can be challenging. The first step should be prevention, which involves patient selection, timing of implantation, and the procedure itself. After implantation, a high degree of suspicion should be applied in order to correctly diagnose patients with infected implanted devices. It is necessary to recognize that patients can present with a wide variety of signs and symptoms. Once diagnosed, the next step is determining if it is a local pocket infection or system infection. In almost every patient, in addition to antibiotics, complete removal of ALL hardware is required. Transvenous lead extraction is now safe and effective, but should only be performed at experienced centres with a practiced extraction team, all possible needed equipment, and cardiothoracic surgical backup. After extraction, the indication for CIED therapy should be re-evaluated to determine re-implantation is warranted. Timing of re-implantation depends on a variety of factors such as type of infection or valvular involvement and should be made in concordance with an infectious disease specialist. This review is aimed at introducing the steps needed to manage patients with infected cardiac devices.

Keywords
Cardiac implantable devices • Infection • Extraction

Introduction
The number of cardiac implantable electrophysiological devices (CIED) is increasing rapidly over the last decade. This has been mainly due to the increase in implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy (CRT) device implantations secondary to changes in indications and increasing physician awareness of these indications. Clinicians taking care of this patient population unfortunately often encounter patients presenting with suspected local (i.e. pocket) or systemic infection. Interestingly, the rate of CIED infection seems to be raising even out of proportion to the increase in device implantation rates. The reasons for this are unclear, but may be related to older and sicker patients receiving these devices. In addition, more patients are surviving to undergo generator changes, which are associated with a higher infection rate. Cardiac implantable electrophysiological device infection is associated with short- and long-term mortality. The 1-year mortality after CIED infection is around 20% which is even higher than the admission mortality rate. Identifying and managing these patients can be very challenging and usually warrants a ‘team approach’ including at least an electrophysiologist/cardiologist and an infectious-disease specialist. On the other hand, surgical tools available for transvenous extraction have substantially improved over recent years, which allows for safer and more effective removal of the infected devices. In this review, we will summarize the available data on management of device infections. We wish to emphasize that there are no randomized trials on most of the issues discussed in this review. Therefore, this review expresses our approach to CIED infection management. We do acknowledge that in some of these issues, there may be more than one clinical approach.

Prevention
As in other fields in medicine, the most important step is prevention. The best treatment of CIED infections is to prevent them!

It is noteworthy that antibiotic prophylaxis for routine dental, gastrointestinal, or genitourinary procedures is not recommended, thus prevention is mainly achieved with good anti-septic and surgical techniques both at implant and anytime the pocket is entered. It is important that the implanting physician recognizes risk factors associated with increased CIED infection. Risk factors...
have been extensively studied. They can be divided into two main groups, those that are patient-related and those that are procedural-dependent. Patient-related factors include diabetes mellitus, congestive heart failure, chronic renal failure, long-term use of corticosteroids, patients with existing central lines such as dialysis lines, patients on anticoagulants, and, maybe, most importantly patients with a fever within 24 h of implantation.9–11 Procedural factors include longer procedure time, operative inexperience, use of temporary pacing leads, dual- or triple-chamber devices, lack of antibiotic prophylaxis, and development of post-operative pocket haematomas. Several studies have suggested that infection rates associated with generator implantations are higher with replacements compared with initial implantation.10–15 It is of interest that cultures taken from fibrotic capsules in clinically uninfected patients have yielded staphylococci species.16 These findings emphasize the high burden of bacteria in the pacemaker pocket, which increase the risk for infection especially when penetrating the capsule for generator changes. In addition, the fibrous capsule inhibits the body’s normal defense mechanisms from reaching the foreign body. Thus, strict aseptic technique, administration of intravenous (IV) antibiotics, verification of the absence of systemic infection symptoms prior to implantation and shortening procedure time could all aid in preventing future CIED infections. Sterile technique must be ‘OR’ sterile technique, as opposed to, ‘cath lab’ sterile technique. All staff must be trained appropriately and the room must be treated as an operating room. This includes the room having OR quality ventilation, careful setup of tables, and preparation of the patient, as well as strict limitation to room traffic. Prophylactic antibiotic administration has been proved to lower infection rates.17 *Staphylococcus aureus* (SA) are by far the most common organism involved in CIED infections. Up to almost 50% of those were found in several studies to be methicillin resistant (MRSA).3,17,18 Therefore, the IV antibiotics administered should at least cover SA species. Currently, there are no clear guidelines whether an MRSA covering agent should be administered prophylactically for every implantation or if MSSA coverage is sufficient. This should be guided by the prevalence of MRSA in the implanting institution. Some advocate that antibiotic therapy should continue for 5 days after implantation.17 There is some data20 that an antibacterial envelope (Aigis RX) locally releasing minocycline and rifampin can prevent CIED infection in high-risk patients, however, prospective randomized studies are lacking. In addition, removal of these pouches can be difficult when required (Figure 1). Elective implants should be postponed, if the patient has a temporary central line. In patients on chronic dialysis, one can consider a simple epicardial VVI pacemaker via a sub-xiphoid approach or limited thoracotomy.21 This can be done with a minimal risk if done by an experienced surgeon and may reduce the risk of systemic infection in the long-term. This approach is less straight forward, but can still be done even if the patient needs dual-chamber pacing. Therefore, in such cases, a risk and benefit of epicardial vs. endocardial should be considered and discussed with patient.

The higher the number of leads implanted, the higher the risk for infection (Figure 2). Therefore, other aspects of planning to prevent potential infection complications include balancing risks and benefits of the need for dual-chamber vs. single-chamber devices. This becomes especially relevant when implanting ICDs in patients with no need for pacing. One should also ask if there is need for a dual-coil ICD lead or is a single-coil ICD lead sufficient for arrhythmia prevention purposes. Dual-coil leads may increase the procedural extraction risk if needed in the future. In general, one cannot emphasize on how important it is to minimize and implant only necessary hardware. Unnecessary hardware may not only increase the risk for infection, but increase the risk for major complications during the extraction procedure.22

During implantation, care should be taken to achieve complete haemostasis in the pocket. Most microbiology labs use blood as the culture medium for their bacterial cultures. Therefore, avoiding a pocket haematoma is a crucial part of infection prevention. Uses of oral anti-coagulants are considered a risk factor for infection.23 There is currently accumulating data that CIEDs can be implanted without stopping chronic anti-coagulation therapy.24 The use of heparin (UFH or LMWH) bridging was associated in these studies and in others with increased pocket haematomas.25,26 Therefore, implanting CIED with a therapeutic INR seems a reasonable approach in avoiding post-operative pocket haematomas which could increase the risk for infection. Of interest, a recent study by Cano et al.24 proposed to interrupt anti-coagulation in patients with low risk for thrombo-embolic events and to continue therapy in patients with moderate-to-high risk for thrombo-embolic events. Continuing anticoagulation with warfarin resulted in lower incidence of pocket haematomas compared with the bridging group. Furthermore, two patients in the bridging group developed pocket infections compared with those managed on oral anti-coagulants. It is still a matter of debate whether capsulectomy of the old pocket capsule should be done at the time of a generator change. Theoretically, capsulectomy should help in revascularization of the pocket allowing better antibiotic penetration, but on the other hand, this could also result in more pocket bleeding/haematoma, which could result in infection. Although evidence-based data is lacking, it is our practice in cases of generator changes to perform at least a partial capsulectomy if not a full capsulectomy to vascularize the old device pocket.
In summary, a relatively high percentage of the known risk factors for CIED infection can be prevented at the time of the implantation. Early recognition is crucial to management and in preventing future complications.

**Diagnosis**

The presentation of CIED infection can be obvious in some cases; however, the diagnosis can pose a significant challenge in others. Presentation can include a wide range of symptoms. Symptoms can include anything from local pocket erosion to full-blown sepsis. In one study, findings included fever (45%), chills (43%), erythema (41%), swelling (38%), drainage (38%), tenderness (28%), malaise (28%), erosion (21%), and warmth (18%). Specifically, pocket tenderness or swelling can be secondary to other reasons such as pocket haematoma. Therefore, a high degree of suspicion is required. Erosion can be a manifestation of infection or skin breakage due to frail skin commonly encountered in older patients or patients on, for instance, chronic steroid therapy (Figure 3). Regardless of the reason, once exposed, the generator and leads become contaminated. Therefore, every pocket erosion case should be treated as pocket infection. In the MEDIC (Multicenter Electrophysiologic Device Infection Cohort) registry, the most important factor in distinguishing between local and systemic infections was time from implantation. While patients with <6 months since implantation more frequently presented with signs of local pocket infection, the majority of patients with >6 months since implantation presented with signs of systemic infection. Of note, one should not disregard or underestimate the significance of a local infection. In a study by Klug et al., 72% of the 50 patients presenting with local pocket infection had positive cultures of the intravascular lead segments. This finding was regarded by the authors as a proof for micro-organisms migration from the pocket along the lead into the vascular bed although contamination from the pocket cannot be excluded. Our experience is in concordance with this study, showing that if local infection is left untreated it may develop into systemic infection, highlighting guidelines recommendation for early removal.

Once CIED infection is suspected, it is essential to obtain at least two sets of blood cultures (class Ic indication). This should be done prior to antibiotic therapy. In reality, most patients are started on antibiotic therapy even for suspected local infection prior to referral to an extraction centre. The main reason for negative blood cultures in the setting of CIED endocarditis is probably prior antibiotic treatment. Positive gram-positive blood cultures even in the absence of systemic signs of infection should always raise suspicion of CIED infection. It is important to note that gram-negative bacteraemia does not exclude CIED infection. White-blood count is not always useful as it is often within normal range. However, the presence of leucocytosis or elevated
C-reactive protein at baseline can be useful to follow the response to therapy. Generator pocket tissue and lead tip culture should be obtained during the extraction procedure (class Ic indication). The most common source of positive cultures is usually the lead tip, followed by blood and pocket tissue. This will allow the identification of common pathogens such as coagulase negative staph which when drawn from the blood are often considered a contamination.

In one study, pocket-tissue cultures were positive only in 44% of the cases. Still sensitivity of pocket-tissue culture is higher than swab culture of the pocket. Percutaneous aspiration of the pocket has a low diagnostic lead and in fact can increase the chance of local infection by introducing micro-organisms into the pocket that may not be infected! Therefore, it is contra-indicated (class III indication). Transoesophageal echocardiography (TEE) should be done if blood cultures are positive or when systemic signs of infection are present. Transoesophageal echocardiography can help not only to identify the lead vegetations but also rule out valvular endocarditis or myocardial abscesses. We, therefore, recommend to also perform a TEE in all patients with CIED infection and prosthetic valves. It is of note that an incidental mass can be noted on up to 5–10% of the leads, with no significant increase in morbidity or mortality. Masses seen on TEE can also be secondary to thrombus. The most common place for incidental masses is the right atrium aspect of the lead. Therefore, TEE reading should be done in the context of the clinical picture. In patients with SA bacteraemia, the rates of lead vegetation on TEE is high. One should also consider TEE in patients who have negative cultures but blood cultures were taken after prior antibiotic therapy. Transthoracic echocardiography should also be considered as it can provide additional valuable data prior to extraction such as ejection fraction, and a baseline of both tricuspid regurgitation and pulmonary hypertension. In difficult cases, other modalities to be considered are 3-D TEE and FDG-PET/CT scanning. Radiolabelled leucocyte scintigraphy has been described as additive tool in the diagnosis of endocarditis, however, its role is not established. Intra-cardiac echocardiography which is nowadays an established imaging tool in the electrophysiology laboratory was found to identify scar tissue along the leads and might have a future role in detecting intravenous extra-cardiac lead vegetations which cannot be detected by TEE.

In summary, even after obtaining blood cultures and performing adequate imaging, decision reaching is not always straightforward. In cases with incidental TEE finding of a mass on a lead, in the absence of local or systemic infection signs, and repetitive negative blood cultures there is no need for immediate intervention. However, the patient does need close follow-up. If blood cultures are positive and there is no sign of pocket infection or masses suggestive of vegetations on TEE, the first step should be to look for other sources of bacteraemia. If there is no other obvious source for gram-positive bacteraemia, CIED infection should be presumed and the CIED system should be extracted. Cases with gram-negative bacteraemia should be managed more conservatively in terms of CIED extraction. If there are no vegetations and a source is discovered, a trial of antibiotics should be considered. In all of these, it is essential to manage the patient as a team including an electrophysiologist and an infectious disease specialist.

Management

In cases of superficial or incisional infection, that do not involve the hardware, there is no need to remove the device. Seven to 10 days of oral antibiotics are usually adequate treatment. Once the diagnosis of CIED infection is made, complete removal of all hardware should be performed, whether the infection is systemic or only involves the pocket. The only exception is when the risk of extraction is considered not indicated due to the age and/or prognosis of the patient. There are occasional cases of pocket infections/erosions in the infirmed elderly that extraction may not be warranted. In these patients, pocket debridement and chronic suppressive antibiotics may be appropriate. In all others, complete removal of all hardware is mandatory. Prior to removal, but after blood cultures, IV antibiotics should be initiated. As previously stated, most CIED infections are secondary to SA and of those up to 50% are MRSA. It is, therefore, our practice and others to administer IV Vancomycin to all pocket or systemic CIED infections unless the bacteria and sensitivities involved are known. In such cases, the IV antibiotic that the bacterium is sensitive to can be administered prior to the extraction procedure. Daptomycin is a reasonable alternative to Vancomycin. There is a lack of evidence on the appropriate length of antibiotic therapy. In general, the American Heart Association update statement on CIED infection recommends 10–14 days of antibiotic therapy after removal for pocket infection and 14 days for bacteraemia. In cases of device endocarditis or complicated bacteraemia (such as persistent bacteraemia, osteomyelitis, or infected thrombophlebitis) 4–6 weeks of therapy is warranted. Staphylococcus aureus bacteraemia typically requires longer therapy than for instance coagulase negative staph bacteraemia. An infectious-disease consult can help to determine the appropriate length of therapy. It is essential to remove all hardware to avoid recurrence of infection. In one study, 71% of patients with retained material showed recurrence of infection. Other studies had lower rates but recurrence rates were evident only in those with retained hardware. This is true for both endocarditis and pocket infections. In patients with pocket infections, a failure to remove ALL of the hardware (device AND leads) not only led to a higher recurrence rate, but also an increased risk of endocarditis and death. In a recent publication from our institution, Kaplan–Meier analysis demonstrated that while there were no procedure-related deaths, there was a cumulative mortality of 2.1% at 30 days, 4.2% at 3 months, 8.4% at 1 year, and 46.8% at 10 years. This data included extractions for all indications. In patients with systemic infection, long-term mortality rates were higher. The unadjusted 1-year mortality approached 25% in this group. Many of these patients were only referred for extraction after failing multiple trials of antibiotics or after a significant delay in diagnosis. One could speculate that the delay to definitive treatment i.e., removal of all the hardware, contributed to these poor, long-term outcomes.

Previously, extraction for infected CIEDs required an open surgical procedure with its inherent morbidity, mortality, and cost, or risky, crude traction devices. With new methods and increased experience, transvenous lead extraction has become the preferred method of removal. It is essential to realize that this can be a high-risk procedure if performed in unprepared centres and in
Complications of cardiac implants

inexperienced hands. However, with careful preparation and a team approach, transvenous lead extraction can be performed both safely and effectively. In the LExICon trial, the use of laser sheaths for extraction was associated with high procedural and clinical success and low major complication and mortality rates. This was true for high and lower volume, experienced extraction centres. Modern mortality rates have been shown to be between 0.1 and 0.6%. Our recent published data showed that in 985 patients undergoing 1043 procedures, there was a major complication rate of 0.5% and there were no procedure-related deaths. In general, data from large series death occurred in up to 0.8% of the cases. These numbers are significantly less than the expected mortality induced by infection. However, even with procedural low mortality rates in experienced hands, transvenous extractions are not without risk. Transvenous lead extraction should be done only in centres committed to a procedural volume allowing maintaining skills of adequately trained teams. In addition, centres performing lead extraction should be able to provide immediate cardiothoracic surgery backup in case of need for emergency thoracotomy or sternotomy. While complications will occur, they do not have to be deaths. We believe delay to definitive surgical repair is a major preventable cause of bad outcomes associated with extraction.

Timing of surgery is crucial not only in patients with sepsis but for every CIED associated bacteraemia. In most cases, one should aim for ‘sooner the better’ for extracting an infected device. However, there are certain considerations that need to be addressed prior to removal. Data from TEE has an important role in decision-making. In patients with need to replace cardiac valves or a cardiac abcess, the CIED system can be removed at the time of cardiac surgery. There is still lack of data on the right approach in cases of large vegetations on TEE. Even vegetations larger than 1 cm have been safely removed transvenously. Some have expressed concern on larger vegetation (i.e. >2 cm). Although safe, some patients experienced symptoms compatible with pulmonary embolism. Other studies have shown that even larger vegetation of up to 7 cm can be removed without causing clinically pulmonary embolism. It is important to note that all vegetations are not the same and size alone is not the only consideration. Some vegetations, although large can be quite ‘stingy’ or ‘friable.’ These usually break up on extraction and do not cause significant pulmonary artery obstruction. However, others are round, large, and dense and could result in significant obstruction. Open surgical removal should be considered in these cases. Therefore, reviewing the TEE images is mandatory in cases of endocarditis with vegetations. One should be cautious in patients with large vegetations and patent foramen oval or any atrial septal defects detected on TEE. In such cases, surgical removal should be considered. Another option would be percutaneous closure of the septal defect prior to the extraction procedure.

When preparing for lead extraction one should carefully choose the appropriate settings. The older the lead, the higher the chance for need of extraction tools such as laser or mechanical sheaths. Per definition extraction is removal of a lead older than 1 year or implantation duration of <1 year but need for more complex tools than simple traction. Other cases that might turn out to be more challenging include ICD leads as opposed to pacing leads, dual-coil ICD leads as opposed to single-coil ICD leads, patients without prior cardiac surgery, and young age. Physical examination is important as it may identify details that may influence the procedure. Such an example includes the presence of chest wall collaterals that may point to venous obstruction. Additional imaging may also be important. All patients undergoing extraction must have a chest X-ray. It is amazing the number of times the extractor is surprised to find additional abandoned leads (Figure 4). In addition, if there is any question on X-ray if the leads are intra-vascular/cardiac, a CT scan should be performed. The heart rhythm consensus document published in 2009 and the European Heart Rhythm Association (EHRA) position paper published this year recommend a minimum of two scrubbed personnel, at least two non-scrubbed personnel, immediate availability of anaesthesiology, cardiothoracic surgeon, and echocardiography. Current guidelines do not state whether the procedure should be done in the EP laboratory or in the OR. In fact, a single study showed that performing extractions in the OR does not offer an advantage over performing them in the EP laboratory with surgical backup. Our own preference is to perform the majority of lead extractions in the OR, under general anaesthesia with the patient prepped for cardiac surgery. We believe that in case of major complications, this will significantly reduce the time to a definitive treatment. Prior to surgery, one should always be prepared with all the various extraction tools that might be potentially used in surgery are indeed available in the room. Interrogation of the device prior to extraction is essential. One must determine whether the patient has a haemodynamically stable rhythm. In many

Figure 4 AP chest X-ray of a patient suffering from lead management gone very wrong. The patient has multiple abandoned and tunnelled leads. This led to SVC syndrome with stenting of the leads in place. The patient developed endocarditis and required an extensive surgical procedure to remove all the hardware. AP, accessory pathway; ERI, elective replacement index; SVC, superior vena cava.
patients, even stable bradycardiac rhythm may become unstable under general anaesthesia. Therefore, even in cases of a stable bradycardiac underlying rhythm, we prefer to discontinue AV nodal blocking agents prior to the extraction procedure and program the device to VVI 40. That way you are not surprised when you disconnect the pacemaker to find the patient no longer has a stable rhythm. If the patient is pacemaker-dependent, a temporary wire should be inserted prior to the extraction procedure. It is our practice to insert a 6FR sheath in right groin for all extraction procedures. This sheath allows access if the need of emergency pacing arises, central access in case of emergency, and for extraction via femoral approach if the need should arise. There are numerous transvenous extraction tools available. Some are designed to be used from the superior approach and others from a femoral approach. Details and techniques of lead removal are beyond the scope of this review and are left to the discretion of the extracting electrophysiologist.

In cases of pocket infection, complete debridement of the pocket is mandatory. Creating a tissue plane outside of the device pocket allows for removal of the entire infected capsule ‘en bloc.’ This is a much easier and more complete approach than removing the device first and then trying to dissect out the remaining capsule. If complete debridement is performed, primary closure is possible in most cases. After irrigating vigorously with an antibiotic solution, a drain is placed and the wound edges are approximated with a mattress suture. In patients with extensive erosion, a primary closure may not be possible. After complete debridement and irrigation, a ‘wound-vac’ is a good option to promote healing by secondary intention. In pacemaker-dependent patients, who are not being implanted at the time of extraction, a ‘semi-permanent’ temporary pacemaker is placed. An active fixation permanent pacemaker lead is positioned in the right ventricle. This is usually placed on the same side as the extraction to preserve the contralateral side for subsequent re-implant. The lead is anchored to the skin and attached to a pacemaker that is exteriorized to the body and secured to the chest wall.

Transvenous lead extraction is a complex procedure necessitating an experienced team approach. One should carefully design the procedure and be confident that all clinical data are gathered prior to the procedure. This includes data from physical examination, device interrogation, and TEE. All equipment and medical personal that might be needed at the time of the procedure must indeed be available. It is essential in cases of an infected CIED that complete removal of all hardware is achieved.

Re-implantation

Data on the optimal timing for re-implantation are limited. It is noteworthy that in a significant number of cases re-implantation is not necessary. Some patients receive a device that may not have been indicated. In others, the indication may no longer exist, such as a patient with sick sinus syndrome who is now in chronic atrial fibrillation with adequate rates. Re-evaluation of the indication for CIED implantation should, therefore, be the first step prior to re-implantation. If a decision has been made that patient will need a device then timing of re-implantation is the next step in the decision process. Factors that may influence such a decision include whether the device was removed for pocket infection, bacteraemia, or endocarditis. Other factors that may be taken into consideration are pacemaker-dependent vs.

Figure 5 A suggested algorithm of managing a patient with an infected cardiac implantable electrophysiological device.
non-dependent, and secondary prevention vs. primary prevention ICD. In cases of bacteraemia, a new device cannot be re-implanted until blood cultures become negative. Some studies have shown that it is safe to implant a device on average 7 days after extraction for pocket infection and after 14 days on average after extraction for patients with bacteraemia cases.45 Prior to removal as much clinical data explanted. It is no longer acceptable to treat CIED infections in infected devices all hardware (device and leads) should be taken before initiation of antibiotic therapy. Once diagnosis necessitates a high degree of suspicion and blood cultures for patients with bacteraemia cases.3,9,43 We make decision on that it is safe to implant a device on average 7 days after extraction until blood cultures become negative. Some studies have shown ICD. In cases of bacteraemia, a new device cannot be re-implanted on a case-by-case basis. In patients with chronic erosions that have drained, we may choose to re-implant on the day of extraction in pacemaker-dependent patients. However, in pocket infections with closed pockets, we worry about the extraction procedure and debridement causing significant bacteraemia and therefore will wait 2–3 days to re-implant. Current guidelines43 recommend that if blood culture were positive before extraction, they should be negative for at least 72 h before new device placement is performed (Ila level of recommendation). In cases of evidence of valvular infection, implantation should be delayed for at least 14 days. The device should be re-implanted on the contralateral side (class I indication) in cases of pocket infection. If patient is at high risk for re-infection (i.e. chronic dialysis patients, etc.), an epicardial pacing system should be considered.

Summary
Management of cardiac device infections can be challenging. Diagnosis necessitates a high degree of suspicion and blood cultures should be taken before initiation of antibiotic therapy. Once diagnosed, the patient should be managed by a team with experience in CIED infections. As a rule, if not contraindicated, in cases of infected devices all hardware (device and leads) should be explanted. It is no longer acceptable to treat CIED infections in a ‘conservative’ manner.45 Prior to removal as much clinical data as possible should be gathered. This includes physical examination, looking for signs of venous occlusion, blood culture results, device/leads data, pacer dependents, and echocardiography (if systemic infection is suspected). A suggested algorithm for management is displayed in Figure 5. The extraction procedure should be performed only at experienced centres with cardiac surgical backup and a team familiar with the various extraction tools, different approaches, and an emergency treatment plan. After extraction, a re-assessment of the indication for device implantation must be performed. If indicated, the timing of re-implantation should be performed on a case-by-case basis, based on indication for extraction, urgency (dependent patients with semi-permanent devices), blood culture results, and clinical status. With an experienced and supportive team CIED infections can be managed effectively.

Conflict of interest: none declared.

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