Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZO FARMACEUTICO
Ufficio 05 - *Attività ispettive e vigilanza*
Viale Giorgio Ribotta, 5 - 00144 Roma

Ai Direttori Generali degli Assessorati alla Sanità delle Regioni e Province autonome

LORO SEDI

PEC

Alla Società Italiana di chirurgia vascolare ed endovascolare
Viale Cortina d'Ampezzo 170,
00135 - ROMA

socvascolare@tiscali.it

Allegato : 1

OGGETTO: stent – graft dispositivi per chirurgia endovascolare per il trattamento dell'aneurisma - Prodotto: Nellix® EndoVascular Aneurysm Sealing System (tutti i modelli / numeri di serie) - Invito alla aumentata sorveglianza dei pazienti già impiantati a seguito dell'azione di richiamo del dispositivo medico "sistema nellix evas" da parte del fabbricante

Con riferimento all'oggetto ed alla precorsa corrispondenza, si informano gli Enti in indirizzo e la Società italiana di chirurgia vascolare ed endovascolare che la Medicines & Healthcare Products Regulatory Agency (MHRA), l'agenzia regolatoria dei medicinali e dei dispositivi medici del Regno Unito, ha informato le autorità regolatorie dell'Unione europea di aver indirizzato alla classe medica interessata un documento tecnico che include ulteriori indicazioni su come rilevare i segnali di malfunzionamento del sistema Nellix EVAS.

Tra gli incidenti segnalati sono contemplati, ad esempio, migrazione significativa del dispositivo, endoleak di tipo I e/o espansione del sacco dell'aneurisma.

Al riguardo, un gruppo indipendente di esperti sul sistema Nellix EVAS della MHRA, il MHRA's Nellix independent Expert Advisory Group, ha elaborato e fornito alla MHRA il documento dal titolo " Features associated with Nellix endograft failure" .

Premesso quanto sopra, si ritiene opportuno trasmettere il citato documento, quale elemento integrativo delle informazioni già rese in materia, e si invitano coloro in indirizzo a dare la massima divulgazione alla presente comunicazione.

La scrivente si riserva di dare aggiornamenti nel caso di eventuali ed ulteriori informazioni.

Cordiali saluti

IL DIRETTORE DELL'UFFICIO
*f.to Lucia Lispi

*Firma autografa sostituita a mezzo stampa, a sensi dell'art.3, comma 2, del d.lgs. n.39/1993

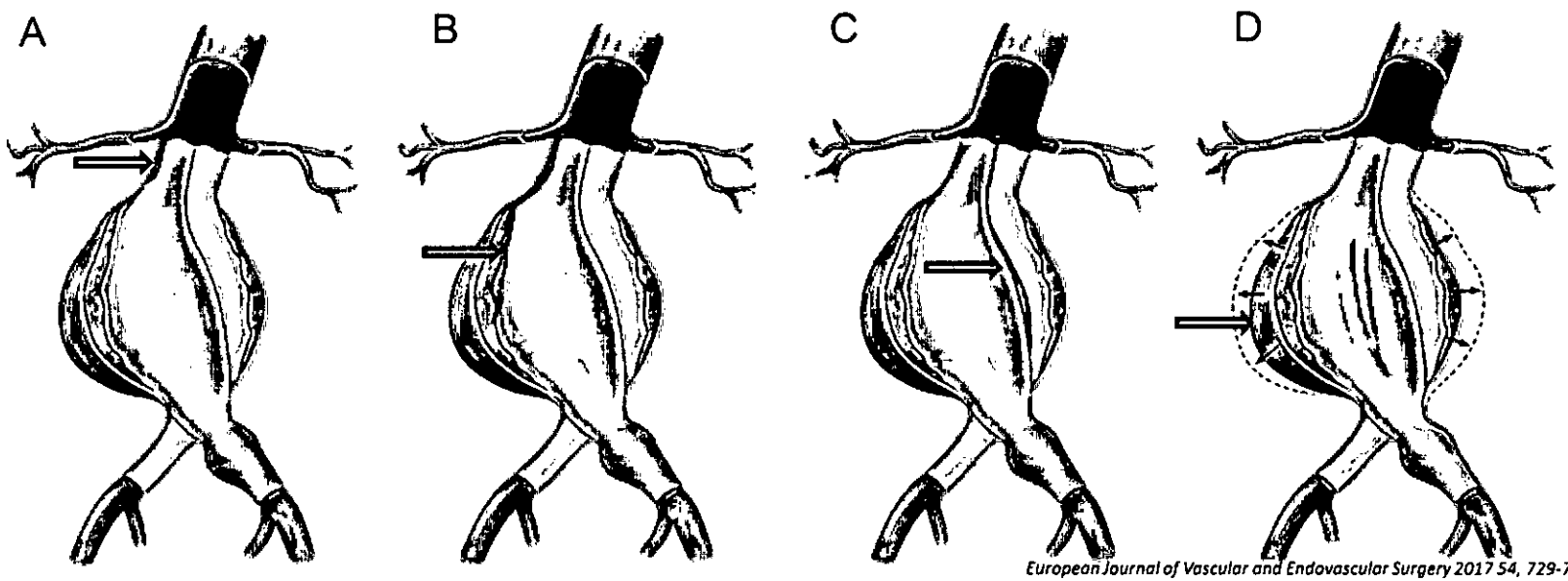
Referente
Dr.ssa Emanuela Fabbri
e.fabbri@sanita.it
tel 0659943733

Features associated with Nellix endograft failure

Produced by the independent Nellix Expert Advisory Group to the MHRA, to complement the following Medical Device Alert:

https://www.gov.uk/drug-device-alerts/nellix-endovascular-aneurysm-sealing-evas-system-device-recall-and-enhanced-patient-surveillance

New classification of type 1 leaks with Nellix



European Journal of Vascular and Endovascular Surgery 2017 54, 729-736

(A) Type Is1 endoleak defined as the appearance of contrast between the endobag and the wall of the proximal neck but not reaching the aneurysm sac itself.

(B) Type Is2 endoleak defined as the appearance of contrast between the endobag and aneurysmal wall or thrombus inside the aneurysm sac.

(C) Type Is3 was defined as the appearance of contrast or fresh thrombus between the endobags inside the aneurysm sac.

(D) Type Is4 endoleak defined as the presence of sac pressurisation without proof or with the presence of secondary signs.

Endoleaks

- In 29% of patients diagnosed with a type 1 endoleak, early signs of the endoleak were identified on imaging that was performed earlier than the reported time of diagnosis and as such were considered a delayed or initially missed diagnosis.

European Journal of Vascular and Endovascular Surgery 2017 54, 729-736

- Early signs of failure tend to progress to later, more significant endoleaks
- Type 1s3, bag separation, is probably the most significant and is present in many late ruptures

USS and AXR

2 MONTHS

The residual aneurysm sac now measures

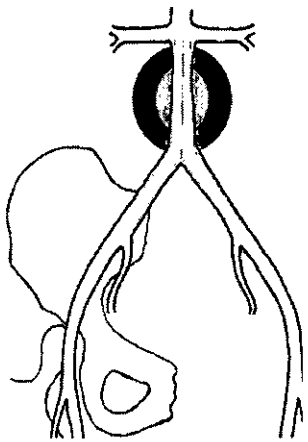
6.8 cm(AP) x 7.0cm(Lateral)

No endoleak detected

BILATERALLY:

Pulsatile biphasic flow in the CFA. No significant disease within the iliac vessels

Note: All diameter measurements are made from outer wall to outer wall



2 YEARS

The residual aneurysm sac now measures:

7.7cm(AP) x 6.3cm(Lateral) - *Sac much larger*

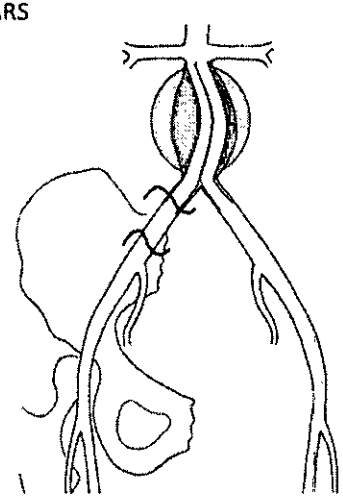
[previously 6.3cm(AP) x 6.8cm(Lateral) 23/02/15]
[6.8cm(AP) x 7.0cm(Lateral) 05/08/15]

No endoleak detected despite good views. No evidence of bag separation

BILATERALLY:

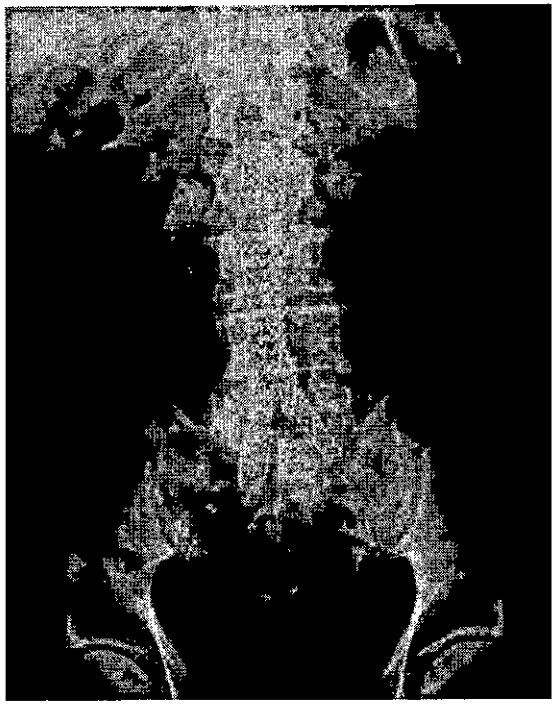
Triphasic flow in the CFA. No significant disease within the iliac vessels (poor views of the RCIA)

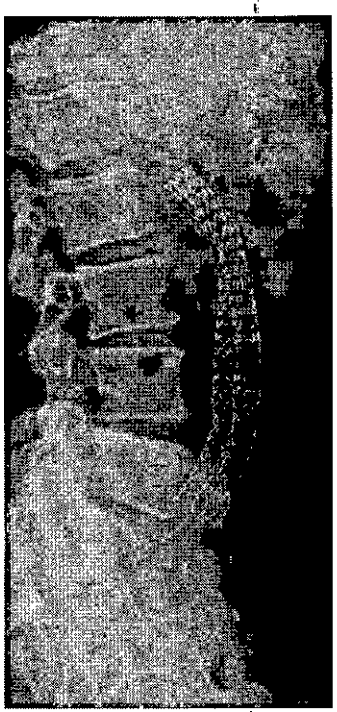
Note: All diameter measurements are made from outer wall to outer wall



- USS is useful method for following up Nellix endografts by measuring sac diameters.
- **It is important that the serial diameter changes are noted so that subtle changes over time can be seen**
- USS can detect some endoleaks but is not sensitive for migration so needs to be combined with AXR

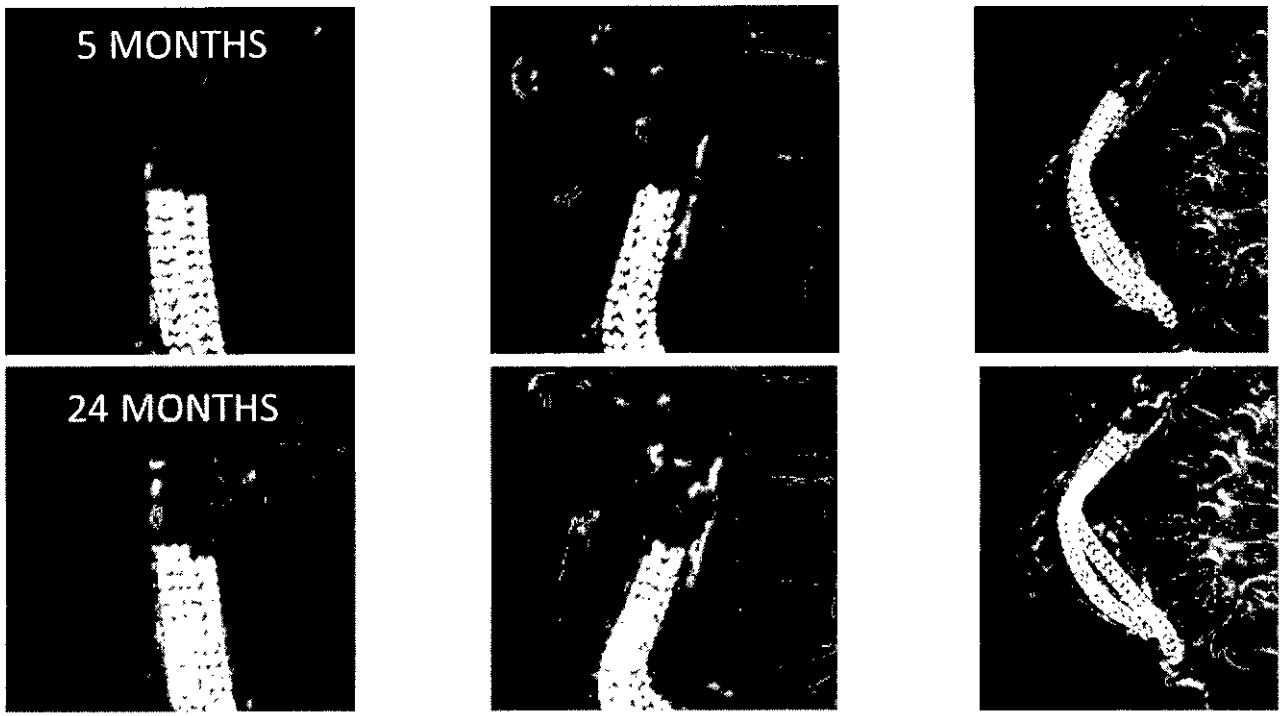
Identifying migration and separation





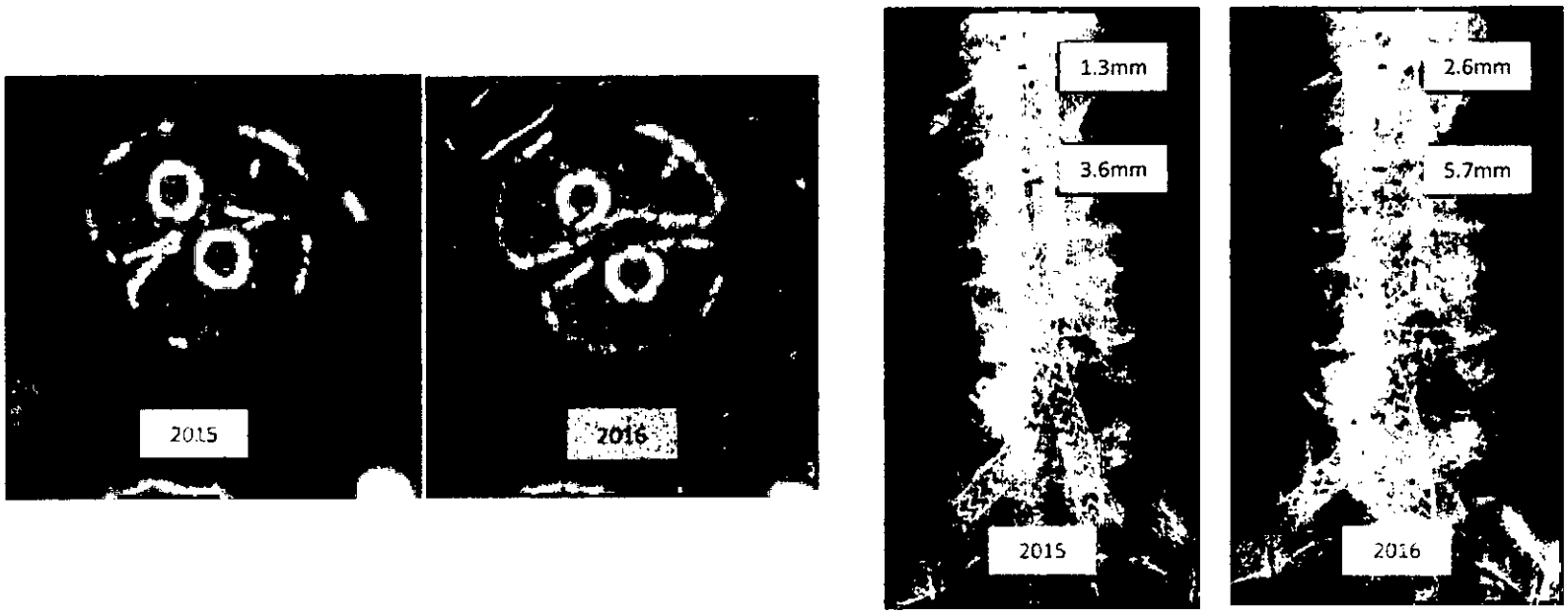
- Migration can be sometimes be seen on a plain x-ray but only if there is a rigid protocol to control height and orientation between AXRs
- Views: AP & Lateral Abdomen
- On the lateral film make sure you are centred to the centre of the stent graft i.e. able to see about 1-2 vertebral bodies above the stent graft and just reach the top of the femoral heads. It is important to see all of the stent graft. Review previous images for stent position to guide follow ups.

Identifying migration



- Best measured from a fixed landmark such as the SMA or renal artery against the first post-op CT scan
- Migration can be sometimes be seen on a plain x-ray but only if there is a rigid protocol to control height and orientation between AXRs
- Increasing mid stent separation with increased curvature of the stents can be a marker for potential migration

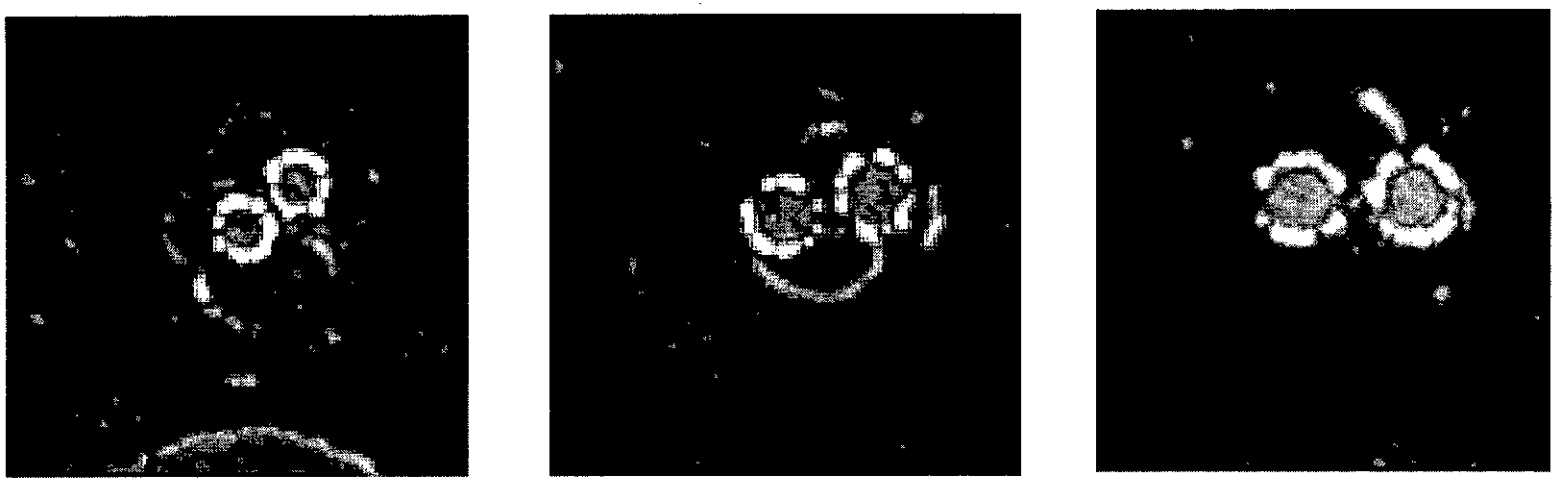
Proximal bag separation



- The inner faces of the bags are tightly opposed after initial bag inflation
- Space developing between the bags or stents on a CT indicates that the thrombus outside the bag has been eroded and there is now pressure transmission into the AAA

Type 1B endoleaks

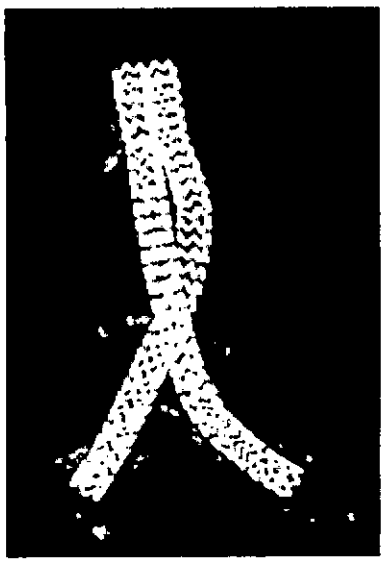
Descending axial images showing the lack of bag seal in the distal aorta

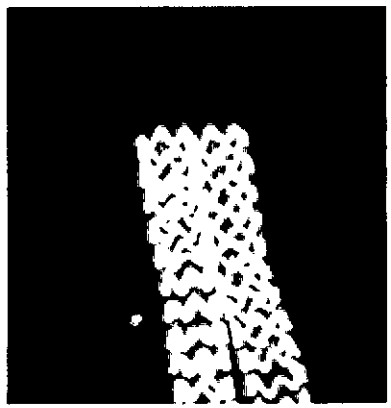


- Type 1B leaks are not always easy to spot and their presence may be underestimated
- On early devices the bags were not attached to the distal ends of the stents and so it is not unusual for the bag to remain in the sac and not seal in the iliac vessels. This is not always easy to appreciate

Type 1B endoleaks

7 MONTHS

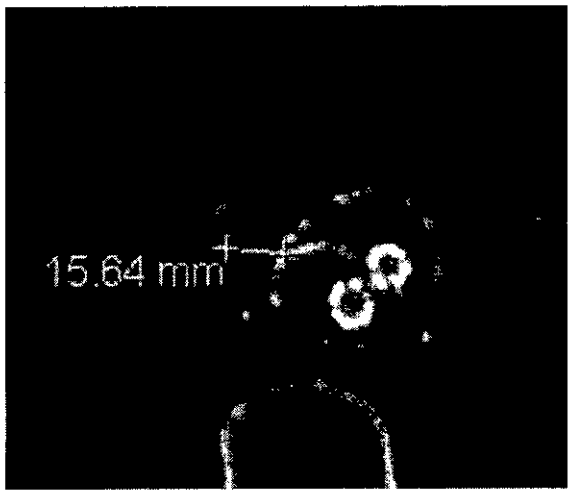


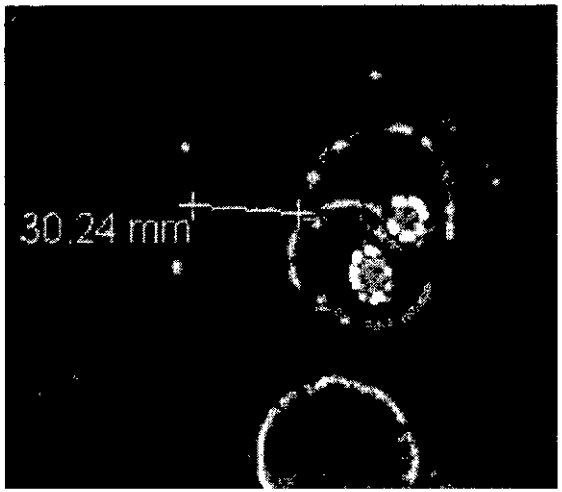


36 MONTHS

- Type 1B leaks are not always easy to spot and their presence may be underestimated
- Increased thrombus accumulation in the lower part of the sac with a stable proximal segment is a warning sign. The key here is that there is mid-stent separation, with increased curvature but that the neck seal has remained intact

Isolated sac expansion





- Increased thrombus accumulation, in the absence of a visible endoleak is an indication that the AAA is pressurised.
- Triple phase CT scans are needed when evaluating for causes of sac expansion.
- The bags can't increase in size, so an expanding AAA is usually due to some form of type 1 endoleak
- Measurements of the distance between AAA edge and Nellix bag can be instructive, as well as measuring stent separation on the axial images.

Summary

- Many Nellix associated endoleaks are not easily visible until clinically significant failure occurs
- Nellix patients need 12-monthly CT scans referenced against the first post-op CT scan
- USS and AXR are also useful but need to be undertaken carefully and referenced to historical images and sizes.
- All Nellix failures should be reported to the MHRA and Endologix