I Dispositivi Impiantabili Attivi RM Conditional nella pratica Clinica.
Neurochirurgia

U.O. Neurochirurgia Modena
Neurochirurgia

- Clips vascolari
- Viti
- Cage
- Valvole ventricolo perotineali
- Deep brain stimulation
- Protesi craniche
- Neurostimolatori
YASARGIL Aneurysm Clip System
Clips for microsurgical treatment of cerebral aneurysms

Description
Then decades of intensive cooperation with leading neurosurgeons all over the world from the foundation for Aesculap’s technical and scientific experience. YASARGIL Aneurysm Clips are the world’s leading clips for the treatment of cerebral aneurysms. Since their introduction, over 2 million clips have been implanted in more than 80 countries. A milestone in the history of neurosurgery. The surgical treatment of cerebral aneurysms will continue to represent an important and indispensable therapy option into the future. The product range of Aesculap is the widest one, including more than 320 different clip designs and 55 applicers (Phynox, titanium, mini, standard, permanent, temporary and fenestrated).

Advantages
▪ Atraumatic blade profile
▪ Atraumatic surface
▪ Sterile packaging
▪ Patented guidance mechanism
▪ Individual serial number

Indication
▪ Surgical treatment of cerebral aneurysms

Properties
▪ MRI examinations using magnetic fields of 1.5 and 3.0 Tesla do not present an additional risk to implant wearers

Note
The clip production has approximately 30 production steps and 70% of those are done by hand. The below movie offers an impressive glance behind the scenes of aneurysm clip production of Aesculap which is located at the Aesculap headquarters in Tuttlingen, Germany.
CranioFix®2

The generation of titanium clamps for quicker application

Description
Since its market introduction in 1997, the titanium clamp system CranioFix® by Aesculap has been an outstanding success. CranioFix® revolutionized bone flap fixation in neurosurgery. The numbers speak for themselves: Over 3.5 million successfully implanted clamps helped patients in over 60 countries. Today, CranioFix®2, the second generation is established worldwide. With even improved speed, ease of use, reliability and efficiency, CranioFix®2 exceeded the success of CranioFix®.

Advantages
▪ Fast and easy application
▪ Excellent reliability
▪ Brilliant stability
▪ Extraordinary smooth and safe operation

Indication
▪ Fixation of craniotomized cranial bone flaps
▪ Fixation of fractures at the brain skull

Properties
▪ Well-known implant-material (Titanium alloy)
▪ High bio-compatibility
▪ MRI examinations using magnetic fields of 1.5 and 3.0 Tesla do not present an additional risk to implant wearers

Brochure CranioFix® 2 Cranial fixation system
Codman Hakim programmable valve (CHPV, Codman & Shurtleff Inc., USA)

Strata valve (Medtronic Neurosurgery, Goleta, CA, USA)

GAV (Aesculap-Miesthke, Tuttlingen/Postdam, Germany)

Programmable valve (ProGAV) with a gravitational unit (Aesculap-Miesthke, Tuttlingen/Postdam, Germany)

ProGAV without a gravitational unit (Aesculap-Miesthke, Tuttlingen/Postdam, Germany)

Pudenz (Heyer-Schulte® Pudenz Flushing valves, Integra™)

Novus valves (Novus™ valve system, Integra™)
Le fonti normative:
La direttiva europea sui Dispositivi Medici Implantabili Attivi
La normativa italiana sull’uso dei sistemi a Risonanza Magnetica
Le linee guida internazionali:
American College of Radiology
European Society of Cardiology
Il consensus document ISS-AIAC-SIRM-FIC-AIFM-AIIC
The presence of a pacemaker or ICD should still be considered a strong relative contraindication to routine MR examination, which is therefore discouraged. MR imaging should only be considered in cases in which the potential benefit to the patient clearly outweighs the risks to the patient.

Risks to the patient are likely increased in centers without highly experienced personnel in both function and programming of the device and operations/pulse sequences of the MR scanner.

Thus, scanning should only be performed at extremely experienced centers with expertise in MR imaging and electrophysiology.

The patient’s heart rhythm and vital signs should be monitored throughout the MR examination.

A physician with pacemaker/ICD expertise should be in attendance during scanning, and a “crash cart,” including a defibrillator, must be available throughout the procedure to address any adverse events.

A person with expertise in MR physics and safety should be involved with the scan to optimally plan the scan to minimize risk. The pacemaker/ICD should be interrogated before and after the procedure.
Amongst the patients with MR unsafe CIEDs, many have conditions that would ordinarily be assessed with MRI. While many can have their medical conditions managed without MRI, in some instances, specific clinical circumstances may present compelling reasons for undergoing an MR examination.

Should MRI be considered, it should be evaluated on a case-by-case and site-by-site basis and only if the site is manned with individuals with the appropriate radiology and cardiology knowledge and expertise on hand.

**Consent:** The patient with a pacemaker or ICD that is not labeled as MR Conditional should be apprised of the risks associated with MRI and should provide informed consent.
Si distingue tra device MR conditional e device convenzionali
• Si riconosce a possibilità di eseguire esami su pazienti con PM/ICD convenzionali, se sussistono importanti indicazioni cliniche (“compelling reasons)
• Si sottolinea l’importanza di un consenso informato specifico
Addendum, Strata®-type Valves, 3.0 Tesla
Tilføjelse, Strata-type ventilører 3.0 Tesla
Addendum, kleppen van het Strata-type, 3.0 Tesla
Addenda, valves du type Strata, 3.0 Tesla
Ergänzung, Ventile vom Typ Strata, 3.0 Tesla
Παραπόθημα, ρακίμαις τύπων Strata, 3.0 Tesla
Kiegészítés, Strata típusú szelepek, 3.0 Tesla
Appendice, valvole di tipo Strata, 3.0 Tesla
Tillegg, Strata-type ventilører, 3.0 Tesla
Dodatek, zastawki Strata, 3.0 Tesla
Adenda, válvulas do tipo Strata, 3.0 Tesla
Anexo, válvulas tipo Strata, 3 TESLAS
Tillägg, ventilor av Strata-typ, 3.0 Tesla
Ek, Strata Tipi Valfler, 3.0 Tesla
Warnings and Precautions - MRI Information

Valves

The Stearn"\textsuperscript{a}, Straub\textsuperscript{b} MDC, and Straub\textsuperscript{c} valves are considered MRI compatible according to standard in accordance with ASTM F1935.

MRI systems of up to 3 T are generally used for lower field strength and will not damage the Stearns, StraubMDC, or Straub valves.

The crest of the valve is located on a surface that can change the performance of the valve and will not affect the MRI system.

The values of the valves are tested for a range of field strengths up to 3 T in order to ensure compatibility.

- Stearns (field of 1.5 Tesla or less)
- StraubMDC (field of 3.0 Tesla or less)

Values are tested at a previously specified number of cycles of 3 T per 10 minutes. MRI systems that pass the above test procedure are considered compatible with MRI devices.

The table provides the maximum signal intensity for the specified pulse sequences at 3 T. The table is based on the tests performed on an MRI system that meets the above criteria.

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>Pulse Sequence</th>
<th>Max Signal Intensity (SI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1-10</td>
<td>crusher</td>
<td>32.19</td>
</tr>
<tr>
<td>T1-30</td>
<td>crusher</td>
<td>32.03</td>
</tr>
<tr>
<td>0.64</td>
<td>crusher</td>
<td>32.07</td>
</tr>
<tr>
<td>0.64</td>
<td>crusher</td>
<td>81.11</td>
</tr>
</tbody>
</table>

Adjustment Kits

Do not use the adjustment tool of an MRI facility as these magnets could potentially be a safety hazard to the patient and MRI user. Proceed with caution when using the provided tools due to the risk associated with MRI magnets. Always proceed with caution prior to attempting to modify valve settings.
Prosepective Study to Evaluate Rate and Frequency of Perturbations of Implanted Programmable Hakim Codman® Valve after 1.5-Tesla MRI.

Capitanio JF, Venier A, Mazzeo LA, Barzaghi LR, Acerno S, Mortini P.
PMID: 26455768
Maschio, 83 anni
DVP valvola strata per idrocefalo normoteso
TAO per fibrillazione atriale
RM per controllo
Maschio 71 anni
DVP valvola strata per idrocefalo normoteso
RM osteoarticolare
Femmina 78 anni
Da 2 settimane confusione, rallentamento
Nel 1987 protesi staffa AU Dx
Anacusia Dx
Femmina 38 anni
K mammella maggio 2014
Espansioni mammari no RM compatibili
Gennaio 2015 TIA?
Maschio 17 anni
A 7 anni diagnosi di epilessia temporale
Gravi difficoltà apprendimento, dislessia
A 12 anni cambio di mano nello scrivere
A 17 aa coma, emiplegia dx
Take home message

1. controllo valvole DVP dopo RMI

2. eseguire RMI encefalo in pazienti con lesioni intracraniche