RAPID HTA REVIEW		
N° richiesta	**Data richiesta**	**Richiedente**
262	Giugno 2022	Cardiochirurgia - AOUC
Tipo di scheda		
Nuova scheda		SI
Aggiornamento di una scheda precedente		NO
Se aggiornamento, indicare il motivo:		

Dati generali della tecnologia in valutazione			
Nome commerciale			
HAART 300 Device per anuloplastica aortica			
Nome generico			
Dispositivo per anuloplastica aortica tricuspidale			
Nome fabbricante			
BIOSTABLE Science & Engineering INC			
Nome fornitore			
LeviBIOTECH SrL			
RDM	**REF**		
Mis 19 RDM 1424384 Mis 21 RDM 1425431 Mis 23 RDM 1425433 Mis 23 RDM 1425440	COD. 300-19 COD. 300-21 COD. 300-23 COD 300-25		
Tipo	**Marchio CE (data)**	**Classe di rischio**	**Approvazione FDA**
1	Certificato n. 631051 (data 2021-04-26)	III	SI
CND			
P07030402 (ANELLI VALVOLARI CARDIACI RIGIDI O SEMIRIGIDI CON SUPPORTO)			
Campo di applicazione			
Cardiochirurgia			
Paziente target			
Pazienti che presentano insufficienza aortica di grado moderato/severo con dilatazione del solo anulus aortico e non dei seni di Valsalva. Si tratta di pazienti che spesso presentano concomitante insufficienza mitralica o by-pass aorto-coronarico. L'impiego di HAART 300 avverrebbe con approccio mininvasivo se monovalvolare o sternotomico se occorre correggere entrambe le insufficienze (aortica e mitralica).			
Indicazione d'uso da scheda tecnica			
HAART 300 è indicato per la correzione della dilatazione anulare e/o il mantenimento della geometria anulare della valvola aortica in pazienti sottoposti a riparazione a seguito di valvulopatia aortica. E' progettato per ripristinare la normale geometria anulare aortica con lembi di diverse dimensioni e per supportare la funzionalità dei lembi			

mediante il recupero della normale geometria e area di coaptazione. Il dispositivo è destinato all'uso in pazienti con morfologia valvolare tricuspide.
Principali competitor
Plastica sub-commissurale o sostituzione valvolare.

Dettagli tecnologici
Descrizione
Il dispositivo per anuloplastica aortica HAART 300 è dotato di tre componenti: 1. Dispositivo per anuloplastica impiantabile: costituito da un telaio in titanio medicale 6AL-4V ricoperto in poliestere. HAART 300 è realizzato in 4 misure da 19 a 25 mm, con incrementi di 2 mm. La sua geometria consente il corretto avvicinamento dei lembi della valvola aortica e aiuta a ripristinare il normale funzionamento valvolare. Il telaio in titanio offre la rigidità necessaria per ripristinare la normale geometria in caso di annulus dilatato, mentre il tessuto in poliestere favorisce l'endotelizzazione e la sutura diretta dei gambi sotto commissurali all'annulus della valvola aortica. Gli aspetti interni dei gambi del dispositivo sono costituiti da 2 strati di tessuto in poliestere per facilitare l'esecuzione della sutura. 2. Pledget in poliestere: hanno dimensione 3 x 7mm e sono realizzati nello stesso tessuto in poliestere del dispositivo. Sono destinati all'uso con il dispositivo per anuloplastica durante l'intervento chirurgico. 3. Supporto per il dispositivo: il supporto può essere avvitato su una impugnatura per facilitare il posizionamento del dispositivo durante la procedura. Il supporto è realizzato in polifenilsulfone ed è agganciato al dispositivo per anuloplastica mediante un'unica sutura.
Elementi di innovazione
Data la complessità della situazione clinica in cui il DM è indicato, la limitata frequenza della stessa, e la difficile identificazione delle alternative terapeutiche a HAART 300, le valutazioni sull'innovazione di questo DM non sono, da un lato, riconducibili ai criteri posti dalla Delibera sull'innovazione intesa come innovazione breakthrough. D'altro lato, appare complessa anche la collocazione di questo DM nel perimetro delle innovazioni incrementali.

Evidenze cliniche ed economiche
Studi clinici
Nove studi sono stati selezionati da PubMed usando "HAART 300" come parola chiave (ricerca del 15 Novembre 2022). I rispettivi abstract sono presentati nell'Appendice. Questi 9 articoli riportano esperienze aneddotiche condotte su casistiche di limitatissima numerosità. Fa eccezione lo studio di Mazzitelli et al (2016), l'ottavo tra quelli riportati in Appendice: posto che la casistica include 65 pazienti, l'impostazione dello studio è quella di un semplice resoconto dell'esperienza condotta in alcuni centri ubicati in Germania.
Sperimentazioni cliniche
Non riscontrate
Linee guida
Non riscontrate
Analisi di costo-efficacia, report HTA
Nessuno
Prezzo value-based
Non calcolabile mancando le informazioni necessarie allo scopo

Benefici attesi
Miglioramento degli esiti; il miglioramento è difficile da definire e da quantificare non essendo univoco quale sia il, comparator da prendere in considerazione.

Prezzo e costo terapia per paziente

Prodotto (Fabbricante)	Prezzo unitario (euro)	Costo terapia per paziente (euro)	Fabbisogno annuo (N, pezzi)
HAART 300	3.500+IVA	3.500+IVA	N=30

Prezzo e costo terapia per paziente con le alternative terapeutiche già in uso

Prodotto (Fabbricante)	Prezzo unitario (euro)	Costo terapia per paziente (euro)
BIOPROTESI VALVOLARE INSPIRIS RESILIA	3.590+IVA	3.590+IVA

Valutazione di innovatività (secondo Delibera regionale N° 737/2022, cliccare qui)	
Dispositivo innovativo (S/N)	NO
Se sì, indicare quali Criteri 1, 2 e 3 risultano soddisfatti:	

Rimborso procedura legata all'uso del dispositivo medico richiesto

Codice ICD9-CM di diagnosi principale (descrizione)	Codice ICD9-CM di intervento (descrizione)	Codice DRG (descrizione)	Tariffa (euro)
Non univoco	35.11	104 (Interventi valvole cardiache e altri interventi maggiori cardiaci)	22.115

Dati riassuntivi

Numero richiesta	Data richiesta	Richiedente
262	Giugno 2022	Cardiochirurgia - AOUC
Tecnologia in valutazione		
Dispositivo HAART 300		
Eventuali esperti esterni coinvolti		
Nessuno		
Conclusioni e parere del Centro Operativo		
Il dispositivo richiesto non può essere ritenuto innovativo (in base alla definizione riportata in Delibera Regionale 737/2022) ma, trattandosi di un'opzione terapeutica che non risulta gestibile per mezzo di DM già contrattualizzati, si esprime parere favorevole. Infatti, il DM va a coprire un "unmet clinical need" poichè offre la possibilità di intervenire con approccio mininvasivo (se monovalvolare) o sternotomico (quando occorre correggere entrambe le insufficienze, aortica e mitralica). Parere favorevole, condizionato all'uso entro la Azienda Careggi ed al fabbisogno annuo indicato dal richiedente.		
Data di redazione della scheda		
15 Novembre 2022		

Estensore della scheda
Andrea Messori
Farmacista aziendale referente per la richiesta
Monica Vaiani

BIBLIOGRAFIA

Vedasi Appendice

APPENDICE

Si riporta l'abstract degli articoli selezionati tramite ricerca PubMed con l'esclusione di un articolo in lingua polacca.

1. Aortic Valve Repair Using HAART 300 Geometric Annuloplasty Ring: A Review and Echocardiographic Case Series
J Cardiothorac Vasc Anesth. 2022 Nov;36(11):3990-3998. doi: 10.1053/j.jvca.2022.03.013. Epub 2022 Mar 19.
Authors
Nika Samadzadeh Tabrizi, Perry Stout, Tanya Richvalsky, Divya Cherukupalli, Anthony Pedersen, Sanjay Samy, Alexander D Shapeton, Sridhar R Musuku.
Abstract
Aortic valve repair (AVr) aims to preserve the native aortic leaflets and restore normal valve function. In doing so, AVr is a more technically challenging approach than traditional aortic valve replacement. Some of the complexity of repair techniques can be attributed to the unique structure of the functional aortic annulus (FAA), which, unlike the well-defined mitral annulus, is comprised of virtual and functional components. Though stabilizing the ventriculo-aortic junction (VAJ), a component of the FAA, is considered beneficial for patients with chronic aortic insufficiency (AI), the ideal AVr technique remains a subject of much debate. The existing AVr techniques do not completely stabilize the VAJ which may increase susceptibility to recurrent AI due to VAJ dilation. An emerging new technique showing promise for the treatment of both isolated and complex AI is AVr using HAART 300TM geometric annuloplasty ring (GAR). The GAR is implanted below the valve leaflets in the left ventricular outflow tract (LVOT), providing stability and creating a neo-annulus. As with other AVr subtypes, this procedure has a learning curve. There are unique surgical and echocardiographic aspects of AVr with GAR, including the appearance of the LVOT, the aortic valve leaflets, and their motion which cardiac anesthesiologists and echocardiographers must be familiar with. In this work, using an eight-patient echocardiographic case series, we provide an overview of this novel AVr technique, including some unique aspects of device sizing, patient selection, expected post-repair echocardiographic features, and a review of outcomes data.

2. A modern approach to aortic valve insufficiency: Aortic root restoration via HAART 300 internal annuloplasty ring
J Card Surg. 2021 Nov;36(11):4189-4195. doi: 10.1111/jocs.15947. Epub 2021 Aug 27.
Authors
Nikolaos A Papakonstantinou, Nektarios Kogerakis, Georgios Kantidakis, Georgios Athanasopoulos, Georgios T Stavridis
Abstract
Background and aim of the study: HAART 300 is an internal geometric annuloplasty ring. The safety and efficacy of this novel device in aortic valve (AV) repair in a single referral center are reported.
Methods: Twenty patients with trileaflet AV insufficiency with ascending aorta and/or aortic root enlargement were included. Subannular implantation was performed to correct annular dilatation, whereas concomitant leaflet repair was performed whenever required. All but two patients also received ascending aorta replacement, whereas selective sinus replacement was performed in all but five patients.

Results: Follow-up was for a maximum of 3.8 years and a mean of 2.2 years. Mean age was 54.2 years old. Moderate to severe preoperative AV insufficiency was noted in 75% of patients, whereas 70% of them had an ascending aorta over 45 mm. One patient was lost from follow-up. Overall mortality as well as major complication rates were zero. Early postoperatively, no more than mild AV regurgitation was detected, whereas only one patient appeared with moderate AV regurgitation during our 2.2-year follow-up. New York Heart Association class was also significantly lower compared to preoperative values and valve gradients remained low at last follow-up.
Conclusions: Geometric ring annuloplasty is a safe and effective valve sparing approach to deal with AV insufficiency contributing to overall root reconstruction. Short-term results are excellent rendering this easily reproducible and versatile method very attractive.

4. Balloon Transcatheter Aortic Valve Replacement After Aortic Valve Repair With HAART 300 Device
Ann Thorac Surg. 2020 Nov;110(5):e375-e376. doi: 10.1016/j.athoracsur.2020.03.090. Epub 2020 May 4.
Authors
Ferdinand Vogt, Jill Marianowicz, Jürgen Jessl, Dennis Eckner, Theodor Fischlein
PMID: 32376351
Abstract
The HAART 300 (BioStable Science and Engineering, Austin, TX) is a rigid, elliptical device introduced to facilitate aortic valve repair providing annular stabilization in the setting of aortic regurgitation. Percutaneous strategies have been described for patients with dysfunctional biological prostheses or recurrence insufficiency after mitral ring annuloplasty. This report shows the feasibility of aortic valve-in-ring transcatheter aortic valve replacement (TAVR). The sufficient ring stability to support the implanted TAVR-prosthesis and the fact that the elliptical shape of the HAART-ring did not result in a problem concerning paravalvular leakage were important for the success of this procedure.

5. Surgical correction of aortic regurgitation using a HAART 300™ rigid aortic ring: A novel method to standardize aortic valve repair
Cardiol J. 2019;26(6):799-801. doi: 10.5603/CJ.2019.0118.
Authors
Radosław Gocoł, Marek Jasiński, Damian Hudziak, Jarosław Bis, Aleksandra Żak, Piotr Duraj, Magdalena Mizia, J Scott Rankin, Marek A Deja
PMID: 31970739
PMCID: PMC8083022

6. Transfemoral transcatheter aortic valve implantation after aortic valve repair with HAART 300 device
Catheter Cardiovasc Interv. 2019 Nov 15;94(6):856-858. doi: 10.1002/ccd.28129. Epub 2019 Feb 17.
Authors
Gyoten Takayuki , Herwig Volker , Harnath Axel, Fritzsche Dirk
PMID: 30773825
Abstract
We report the first successful case, to our knowledge, of CoreValve Evolut R (Medtronic, Minneapolis, MN) implantation into a failed HAART 300 aortic annuloplasty device (BioStable Science & Engineering, TX). An 81-year-old man presented with severe symptomatic aortic regurgitation secondary to failure of the 21 mm HAART 300 device, which had been implanted 45 days previously. Transthoracic echocardiography (TTE) revealed grade 3 aortic regurgitation with central jet, without aortic valve stenosis. Because of the high risk for redo surgery, the heart team proceeded with femoral transcatheter aortic valve implantation. The 26 mm CoreValve Evolut R was deployed into the 21 mm HAART 300 device without difficulty or complications. There were no intraoperative or postoperative complications. The patient was discharged after 5 days. TTE showed a mean aortic valve gradient of 18 mmHg, with minimal paravalvular leak. Our experience suggests that CoreValve Evolut R implantation may be an attractive option in patients with failed HAART 300 aortic annuloplasty.

7. Four-dimensional magnetic resonance after ascending aorta replacement and aortic valve repair with HAART 300 internal annuloplasty ring

J Card Surg. 2022 Nov;37(11):3899-3903. doi: 10.1111/jocs.16950. Epub 2022 Sep 18.
Authors
Joshua S Engel, Sandeep Bharadwaj, Mohammed Elbaz, Michael Markl, Bradley D Allen, S Chris Malaisrie
PMID: 36116051
Abstract
Background: The hemispherical aortic annuloplasty reconstructive technology (HAART) is an internal geometric annuloplasty ring designed to restore a natural elliptical shape to the aortic annulus as part of aortic valve repair. We present four-dimensional flow hemodynamic analysis before and after implementation of the HAART ring in patients undergoing ascending aortic replacement.
Methods: Aortic hemodynamics over the cardiac cycle were visualized using time-resolved three-dimensional pathlines. Velocity streamlines tangent to the time-resolved velocity vector field were used to demonstrate instantaneous aortic hemodynamics. Peak velocities, forward and retrograde flow were calculated at nine planes placed along the midline of the thoracic aorta. Systolic wall shear stress and peak viscous energy loss over the cardiac cycle were calculated.
Results: HAART patients displayed similar or improved flow profiles after surgery when compared to a patient undergoing ascending aortic replacement alone.
Conclusion: There may be a trend towards improved flow dynamics in patients undergoing HAART ring implantation.

8. Geometric ring annuloplasty as an adjunct to aortic valve repair: clinical investigation of the HAART 300 device
Eur J Cardiothorac Surg. 2016 Mar;49(3):987-93. doi: 10.1093/ejcts/ezv234. Epub 2015 Jul 8.
Authors
Domenico Mazzitelli, Theodor Fischlein, J Scott Rankin , Yeong-Hoon Choi, Christof Stamm, Steffen Pfeiffer, Jan Pirk, Christian Detter, Johannes Kroll, Friedhelm Beyersdorf, Charles D Griffin, Malakh Shrestha, Christian Nöbauer, Philip S Crooke, Christian Schreiber, Rüdiger Lange
PMID: 26156945
Abstract
Objectives: This study assessed the safety and efficacy of an internal geometric annuloplasty ring in a regulatory trial of aortic valve reconstruction (ClinicalTrials.gov Identifier: NCT01400841).
Methods: Sixty-five patients with predominant moderate-to-severe trileaflet aortic insufficiency (AI) underwent aortic valve repair with an average age of 63 ± 13 years (mean ± SD). All had initial implantation of an internal aortic annuloplasty ring to correct annular dilatation and facilitate leaflet reconstruction. Leaflet plication was performed for prolapse in 80% of patients, and more complex leaflet procedures, usually employing autologous pericardium, were required in 22%. Ascending aortic and/or root aneurysms were replaced in 62%.
Results: Follow-up was for a maximum of 3 years and a mean of 2 years. No in-hospital operative mortalities, major complications or early or late valve-related events occurred. The annular diameter before repair was 26.5 ± 2.3 mm, and the average ring diameter used was 21.5 ± 1.6 mm. The preoperative AI grade (0-4) was 2.9 ± 0.8 and improved after repair to 0.6 ± 0.7 ($P < 0.0001$), as did the NYHA class. The mean valve gradient was 8.6 ± 4.3 mmHg, and at 3 years, the Kaplan-Meier survival rate was 95%, with no valve-related mortality. Over the 3 years, aortic valve replacement was required in 7 patients (10.8%) for reasons usually related to surgical technique. Most repair failures occurred early, and results stabilized after 6 months. No structural complications of the rings were observed.
Conclusions: Geometric ring annuloplasty was a safe and effective adjunct to aortic valve repair. Initial correction of annular dilatation seemed to facilitate overall reconstruction. Because most early repair failures were technical, increasing experience with geometric ring annuloplasty for aortic valve reconstruction has the potential to standardize and improve outcomes.

9. Aortic valve annuloplasty with the HAART geometric ring and ascending aorta replacement
Multimed Man Cardiothorac Surg. 2018 May 2;2018. doi: 10.1510/mmcts.2018.024.
Authors
Marek Jasinski, Scott Rankin
PMID: 29750406
DOI: 10.1510/mmcts.2018.024
Abstract

Approximately one-third of patients suffering from aortic insufficiency (AI) present also with an ascending aortic aneurysm. AI is most commonly due to a combination of sinotubular junction and annular dilatation. Valve reimplantation or prosthetic valve replacement may not be ideal for these patients, and ascending aortic aneurysm resection with aortic valve repair using geometric internal ring annuloplasty is a simple, successful, and reproducible alternative treatment approach. In this video tutorial we demonstrate aortic valve repair using the HAART 300 annuloplasty ring with concomitant ascending aorta replacement.

Copia del documento può essere scaricata dal sito Internet http://www.regione.toscana.it/-/prodotti-hta.

Redazione a cura del Centro Operativo istituito con decreto n.17610 del 7 Settembre 2022.