

K960356
3/27/96

Summary of Safety and Effectiveness

MEDTRONIC® POSTERIOR ANNULOPLASTY BAND

I. General Information

Device Generic Name: Annuloplasty Band

Device Trade Name: MEDTRONIC® POSTERIOR ANNULOPLASTY BAND

Applicant's Name: MEDTRONIC® Heart Valves, Inc.

Applicant's Address: 18011 South Mitchell
Irvine, CA 92714

II. Description of the Diseases and Conditions for Which the Device is Intended

The MEDTRONIC® POSTERIOR ANNULOPLASTY BAND is indicated for the reconstruction and/or remodeling of the pathological mitral valve. Combined mitral valve stenosis and insufficiency may be corrected by appropriate commissurotomy and valvular remodeling.

The MEDTRONIC® POSTERIOR ANNULOPLASTY BAND is contraindicated for use under the following conditions: the presence of heavy valvular calcification, valvular retraction with severely reduced mobility and the presence of active bacterial endocarditis.

III. Device Description

The MEDTRONIC® POSTERIOR ANNULOPLASTY BAND is constructed of a polyester fabric enclosing an open strip of pliable radiopaque silicone elastomer impregnated with barium sulfate which enables radiographic visualization. The band is uniformly 3 mm in diameter and is provided in a single length of 63 mm. Colored suture markers, which facilitate implantation, are circumferentially located at the center of the band and at each end.

The MEDTRONIC® POSTERIOR ANNULOPLASTY BAND will be offered in one length, 63 mm and will not be mounted onto a holder. No sizes will be offered with the posterior band configuration as only one length is available.

The MEDTRONIC® POSTERIOR ANNULOPLASTY BAND will be supplied in a sterile double aseptic transfer pouch. The annuloplasty band will remain sterile if the pouch is undamaged and unopened.

The MEDTRONIC® POSTERIOR ANNULOPLASTY BAND uses the same materials and is processed, packaged and sterilized similarly to the MEDTRONIC® DURAN FLEXIBLE ANNULOPLASTY RING.

IV. Alternatives

Alternatives for patients requiring mitral valve annuloplasty is valve replacement surgery. Alternatives to use of the MEDTRONIC® POSTERIOR ANNULOPLASTY BAND is commissural annuloplasty and other commercially available annuloplasty bands or rings.

V. Potential Adverse Effects

Potential adverse effects of annuloplasty includes thromboembolic events, ring dehiscence, hemolysis, stenosis, uncorrected or residual incompetence, heart block, and endocarditis.

VI. Summary of Studies

Clinical Experience:

Appendix 3 contains a copy of a published report comparing the clinical experience of posterior annuloplasty (This report details clinical experience utilizing 2/3's of a MEDTRONIC® DURAN FLEXIBLE ANNULOPLASTY RING.) with that of commissural annuloplasty and full ring annuloplasty.

In addition, the MEDTRONIC® DURAN FLEXIBLE ANNULOPLASTY RING has an established clinical record of documented performance for over 15 years. The MEDTRONIC® Posterior Annuloplasty Ring is composed of identical materials and is manufactured utilizing the same assembly, packaging and sterilization operations as the Duran Ring. Thus, the established clinical history of the Duran Flexible ring is germane to the MEDTRONIC® POSTERIOR ANNULOPLASTY BAND. Copies of publications documenting this performance can be found in Appendix 3.

Biocompatibility of Materials/Finished Device:

Cytotoxicity and Hemolysis testing was performed. This testing was performed in accordance with USP requirements.

Qualification:

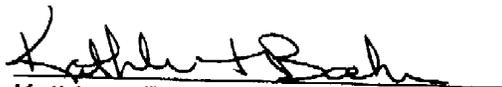
The integrity of the Posterior Annuloplasty Band is considered to be the strength of the band, as measured by the "Wire Pull Out Test". "Wire Pull Out Test" Data for the Duran Flexible Annuloplasty Ring which had been subjected to a 100% Sterilization process (Appendix 9) was presented in an FDA notification provided in October, 1995. The data available for the Duran Flexible Annuloplasty Ring is considered to be germane for the Posterior Annuloplasty Band as the materials and manufacturing processes (inclusive of packaging and sterilization) are similar. The open configuration of the Posterior Annuloplasty Band has no bearing on the results of the "wire pull out test". For your convenience, a summary of this test data can be located in Appendix 5.

A process qualification was performed in order to determine if the band could be manufactured to specifications. The process qualification demonstrated that a pliable band could be produced in accordance with the established product specifications. The process qualification report can be found in Appendix 5.

V. Conclusions

The testing performed for the MEDTRONIC® POSTERIOR ANNULOPLASTY BAND and examination of the clinical experience of the predicate device provides reasonable assurance that the MEDTRONIC® POSTERIOR ANNULOPLASTY BAND will perform in a safe and effective manner when used as indicated.

I believe, to the best of my knowledge, that all data and information submitted in this 510(k) are truthful and accurate, and that no material fact has been omitted.


Kathleen T. Boehm
Product Regulation Manager
MEDTRONIC® Heart Valves, Inc.

1-24-96
Date